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PATENT

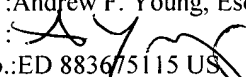
Y3-17

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : **KURTH, Christoph**
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**SUBSTITUTE SPECIFICATION &
SECOND PRELIMINARY AMENDMENT**

MAIL Missing Parts
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SIR:

Kindly enter the enclosed substitute specification and amendment prior to examination on the merits.

IN THE SPECIFICATION

Please cancel the previous specification and replace it with the clean copy enclosed below. As required, a clean version of the specification is attached below.

LINER**Specification**

~~—— The present invention relates to a supporting sleeve for leg or arm stumps, namely a liner, with the features of the preamble of claim 1.~~

~~—— Liners for prostheses, such as leg prostheses, arm prostheses or the like, consisting of a sleeve enclosing the stump from its distal end and made of an elastic, electrically insulating material such as silicone, polyurethane or the like are known (WO 88/00032, WO 98/49977, EP 0 976 371 A1). Such liners are used as a cushioned connection between stump and prosthesis shaft, but are also used postoperatively in order to have a subsiding and shaping effect in the healing phase. It is furthermore known that so-called phantom pain can arise after amputations, and can be positively influenced by electromagnetic screening of the stump, e.g. by an electrically conducting textile material (US Patent 4, 653, 473 A).~~

~~—— The present invention has as its object to provide a liner which has such an alleviating effect against stump pains, but without forfeiting the essential properties of a liner.~~

~~—— The object is attained by the characterizing portion of claim 1. Developments and advantageous embodiments of the invention are included in the further claims.~~

~~—— According to the invention, a supporting sleeve for leg or arm stumps, namely a liner, consisting of a sleeve surrounding the stump from its distal end, is of an elastic, electrically insulating material, characterized in that the sleeve has at least partially a~~

layer of conducting material running around it.

—— According to a first embodiment of the invention, the electrically conducting layer is applied to the sleeve on the outside and consists of a layer of an elastic, conductively equipped textile material or plastic. For example, it can consist of a material onto which metal has been evaporated. Furthermore, for example, the plastic can be applied as an adhesive.

—— According to a second embodiment of the invention, the layer is a textile mechanical reinforcement (matrix), beginning at the distal end of the liner, of an electrically conductive material, the matrix for example consisting of an ordered or unordered threads of a conductive material.

—— According to a particularly advantageous embodiment of the invention, a conductive region is arranged between the stump and the layer of conductive material; the conductive region preferably being arranged at the distal end of the stump.

—— According to an alternative to the preferred embodiment of the invention, the liner has at its distal end a liner cup and if necessary a pin adapter for connection to a prosthesis, the liner cup and/or the pin adapter consisting of an electrically conductive material, or being equipped with such. The liner cup and/or the pin adapter are in contact with the layer of electrically conductive material, the conductive region being arranged between the stump and the liner cup and/or the pin adapter. If the liner is used exclusively for postoperative treatment, the liner cup and pin adapter can be omitted.

—— An electrical resistance of $< 10^3$ ohm is preferably present between the stump and the conductive region.

—— The invention is described in detail hereinafter, by way of example, with use of a drawing.

—— Figure 1 shows a liner 1 of an electrically conductive silicone material, for receiving a leg stump. The liner 1 is provided with a cover 6 of a textile material. A

layer 2 of an electrically conducting material, for example of metal threads, is embedded in the liner 1. At the distal end of the liner there is located a pin adapter 4, known *per se*, for connecting to a lower leg prosthesis. The liner 1 is supported from below by a so-called liner cup 3. Such a construction is known, for example, from DE 100 12 929 A1. The pin adapter 4 and the liner cup 3 consist of metal and are electrically conductive. The liner cup 3 is in contact with the incorporated matrix 2 of electrically conductive material. For producing an electrically conducting connection to the distal end of the stump, an electrically conductive region 5 is arranged above the pin adapter 4, and consists, for example, of a felt of an elastomeric material which is made electrically conductive (evaporated metal, containing conductive carbon) or has through threads of graphite, metal or the like, the electrically conducting region 5 and the liner having substantially the same hardness of material.



Figure 1: ~~"Substitute sheet (Rule 26)"~~

ABSTRACT

~~—— The invention relates to a supporting sleeve for leg or arm stumps, namely a liner, comprised of a sleeve (1) made of an elastic electrically insulating material that surrounds the stump starting from the distal end thereof. Said sleeve (1) has, at least in part, a surrounding layer (2) made of a conductive material.~~

LINER

CROSS REFERENCE TO RELATED APPLICATIONS

5 This application claims priority from PCT/DE03/01835 filed June 4, 2003,
which in turn claims priority from DE 202 08 592.9 filed June, 4, 2002, the contents
of each are incorporated herein by reference.

BACKGROUND OF THE INVENTION

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1. Field of the Invention

The present invention relates to a supporting sleeve for leg or arm stumps,
namely a liner. More specifically, the present invention relates to a liner for surrounding
15 a stump from its distal end with an elastic electrically insulating material, wherein the
sleeve has at least partially a layer of a conductive material.

2. Description of the Related Art

20 The related art involves liners for prostheses, such as leg prostheses, arm
prostheses or the like, consisting of a sleeve enclosing the stump from its distal end and
made of an elastic, electrically insulating material such as silicone, polyurethane. Such
related art liners are shown, for example in WO 88/00032, WO 98/49977, and EP 0 976
371 A1.

25 Such liners are used as a cushioned connection between stump and prosthesis
shaft, but are also used postoperatively in order to have a subsiding and shaping effect

in the healing phase. A common post-surgical routine is to daily apply elastic bandages around the swollen amputation stump to counteract the swelling and accelerate the unavoidable muscle atrophy prior to using a liner. Unfortunately, stump bandaging, if incorrectly performed, may be ineffective and at worst injurious to the patient. After
5 following initial amputation, and after a period using elastic bandages, the resulting stump is fitted to a liner.

Related liners or “sleeve shaped” articles for amputation stumps are known from WO 88/00032 to Klasson, and commonly provide a frusto-conical shape with a truncated end being rounded to receive the stump and a distal end being open to support
10 the stump. As shown in Klasson, such liners often have a clasp or linking mechanism to join the liner to a prosthesis and prevent unintended separation.

It is furthermore known that so-called phantom pain can arise after amputations, and can be positively influenced by electromagnetic screening of the stump, e.g. by an electrically conducting textile material applied in dry contact with the skin. An example
15 of such related art is found in US Pat. No. 4,653,473 to Batters.

As detailed in US Pat. No. 4,653,473, a metal mesh in the form of a glove or sheet may be wrapped about a portion of the body and an electric current is applied at a shock pulse rate sufficient to “reduce pain....without causing heat build-up within the tissue of the human body.” Such treatments are used to sooth arthritis, bone breaks, and
20 other injuries.

However, what is not appreciated by the related art is the prior art is the need to combine the supportive aspects of a liner, with a capacity for every day use of electrotherapy while retaining the ready and secure connection to a prosthesis.

What is also not appreciated by the related art, is that postoperative treatment
25 with elastic bandages may substantially diminished or eliminated and healing promoted by directly employing a liner having an adjustable and useable electrically conductive

region for management of pain and discomfort while providing the same support found in elastic bandages.

Accordingly, there is a need for an improved liner allowing the ready use overcoming at least one of the detriments noted above.

5

OBJECTS AND SUMMARY OF THE INVENTION

An object of the present invention is to provide an embodiment that overcomes at least one of the detriments noted above.

10 Another object of the present invention is to a liner which has such an alleviating effect against stump pain, but without forfeiting the essential properties of a liner.

The present invention relates to a supporting sleeve for a leg or arm stumps, namely a liner. The liner includes a sleeve made of an elastomeric and electrically insulating material that surrounds the stump starting from the distal end thereof. The
15 sleeve has at least in part a surrounding layer made of a suitably conductive material.

According to an embodiment of the present invention there is provided a supporting member for limb stumps, namely a liner, comprising: a sleeve member further comprising at least an elastomeric material, the elastomeric material being elastic and electrically insulating, the sleeve member defining a cavity for receiving a distal end
20 of a stump, portions of the elastomeric material bounding the cavity for receiving the stump, the sleeve member further comprising a surrounding layer, and the surrounding layer composed of a conductive material.

According to another embodiment of the present invention there is provided a supporting sleeve for a stump, namely a liner, comprising: a sleeve member having a
25 shape to bound at least a distal end of the stump, the sleeve member being at least

partially an elastic and an electrically insulating material, and the sleeve member further comprises an electrically conductive layer bounding at least a portion of the stump.

According to another embodiment of the present invention there is provided a supporting sleeve for a stump, wherein: the electrically conductive layer is positioned
5 externally to the sleeve member.

According to another embodiment of the present invention there is provided a supporting sleeve for a stump, wherein: the electrically conductive layer includes at least one of an electrically conductive elastomeric material, an electrically conductive textile material, an electrically conductive ceramic composite, and electrically conductive
10 plastic material.

According to another embodiment of the present invention there is provided a supporting sleeve for a stump, wherein: the electrically conductive layer is a matrix of an electrically conductive material enclosed by an elastic material.

According to another embodiment of the present invention there is provided a supporting sleeve for a stump, wherein: the matrix is one of an ordered and a disordered
15 assembly of thread members of an electrically conductive material.

According to another embodiment of the present invention there is provided a supporting sleeve for a stump, further comprising: means for forming a electrically conductive region between the stump and the electrically conductive layer.

According to another embodiment of the present invention there is provided a supporting sleeve for a stump, wherein: the means for forming a conductive region
20 includes a liner cup member at a distal end of the liner.

According to another embodiment of the present invention there is provided a supporting sleeve for a stump, wherein: the conductive region is arranged proximate one
25 of the distal end of the stump and a non-distal-end region of the stump within the liner.

According to another embodiment of the present invention there is provided a supporting sleeve for a stump, further comprising: a liner cup member at a distal end of the liner.

5 According to another embodiment of the present invention there is provided a supporting sleeve for a stump, wherein: the liner cup member is one of a cup member formed from an electrically conductive material and a cup member coated with an electrically conductive material, whereby the liner cup member

According to another embodiment of the present invention there is provided a supporting sleeve for a stump, wherein: the liner cup member is in an electric
10 communication with the electrically conductive layer.

According to another embodiment of the present invention there is provided a supporting sleeve for a stump, wherein: a measured electrical resistance between a surface of the stump installed in the liner and the conductive region is less than about 10^5 ohms ($<10^5$ ohms).

15 According to another embodiment of the present invention there is provided a supporting sleeve for a stump, further comprising: means for enabling a secure connection between the supporting sleeve and an external prosthesis shaft member.

According to another embodiment of the present invention there is provided a supporting sleeve for a stump, further comprising: the means for enabling a secure
20 connection being one of an electrically conducting means and an electrically insulating means.

According to another embodiment of the present invention there is provided a supporting sleeve for a stump, further comprising: means for forming an electrically
conductive region between the stump and one of the electrically conductive layer and
25 a liner cup electrically connected to the electrically conductive layer and positioned proximate the distal end of the stump.

According to another embodiment of the present invention there is provided a supporting sleeve for a stump, namely a liner, comprising: a sleeve member having a shape to bound at least a distal end of the stump, the sleeve member being at least partially an elastic and an electrically insulating material, the sleeve member further comprises an electrically conductive layer bounding at least a portion of the stump, the electrically conductive layer is not in direct contact with the distal end of the stump, and means for forming a electrically conductive region between the stump and the electrically conductive layer.

The above, and other objects, features and advantages of the present invention will become apparent from the following description read in conjunction with the accompanying drawings, in which like reference numerals designate the same elements.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a cross-sectional view of a liner according to one embodiment of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Reference will now be made in detail to several embodiments of the invention that are illustrated in the accompanying drawing and language. The drawings are in simplified form and are not to precise scale or shape. For purposes of convenience and clarity only, directional terms, such as top, bottom, up, down, over, above, and below may be used with respect to the drawings. These and similar directional terms should not be construed to limit the scope of the invention in any manner. Furthermore, the words "connect," "couple," and similar terms with their inflectional morphemes do not

necessarily denote direct and immediate connections, but also include connections through mediate elements or devices.

Referring now to Fig. 1, a liner 1 having a distal and a proximate end is formed to include, in part, a preferably electrically conductive silicone material, and is shaped for receiving a leg or body stump. Liner 1 is provided with a cover 6 of a textile material. A layer 2 of an electrically conducting material, for example of metal threads or other metal or non-metal electrically conducting, is embedded in liner 1.

At the distal end of liner 1, there is located a pin adapter 4, known per se, for connecting to a lower leg prosthesis. During operation, liner 1 is supported from below by a supporting liner cup 3. In one preferred embodiment, pin adapter 4 and liner cup 3 consist of metal and are electrically conductive although other constructions are contemplated enabling the operation described herein.

Liner cup 3 is in contact with the incorporated matrix 2 of electrically conductive material.

For producing a therapeutically effective electrically conducting connection to the distal end of the stump, an electrically conductive region 5 is arranged above the pin adapter 4, and consists of, for example, a comfortable or felt-feel of an elastomeric material which is made electrically conductive by its construction (for example it contains evaporated metal, containing conductive carbon, etc.) or has through threads of graphite, metal or the like contained therein or surrounding on a contact surface.

In a preferred construction, electrically conducting region 5 and liner 1 having substantially the same hardness of material whereby a stump inserted within the proximate end of liner 1 is received by surfaces having a similar therapeutic feel.

According to one alternative of the present invention, a supporting sleeve for leg or arm stumps, referred collectively to herein as a liner, consists of a sleeve surrounding the stump from its distal end, is of an elastic, electrically insulating material,

characterized in that the sleeve has at least partially a layer 2 of conducting material running around it.

According to another embodiment of the invention, the electrically conducting layer 2 is applied to the sleeve on the outside and consists of a layer of an elastic, conductively equipped textile material or plastic. For example, electrically conducting layer 2 may optionally consist of a material onto which metal has been evaporated, adhered to, or otherwise applied enabling the conduction of electricity. Furthermore, for example, the plastic can be applied as an adhesive.

According to another embodiment of the invention, layer 2 is a textile mechanical reinforcement (formed as a matrix), beginning at the distal end of liner 2, of an electrically conductive material. As envisioned in this alternative embodiment, the matrix for example consists of an ordered or unordered threads, or a combination thereof, of a conductive material.

According to one particularly advantageous embodiment of the invention, a conductive region is arranged between the stump and the layer of conductive material 2, the conductive region preferably being arranged at least the distal end of the stump.

According to an alternative to the preferred embodiment of the invention, liner 2 has at its distal end a liner cup 3 providing support and if necessary a pin adapter 4 for connection to a prosthesis or other device. Here, liner cup 3 and optionally pin adapter 4 consist of an electrically conductive material, or being equipped with such effective to enable a therapeutic electromagnetic field proximate the distal end of liner 2.

Liner cup 3 and/or pin adapter 4 are in electrically connection with layer 2 of electrically conductive material, the conductive region being arranged between the stump and the liner cup 3 and/or the pin adapter 4.

It is recognized herein, that if liner 1 is used exclusively for non-weight-bearing postoperative treatment only, the liner cup 3 and pin adapter 4 may be omitted.

In another alternative embodiment of the present invention, an electrical resistance of $< 10^5$ ohm (less than about 10^5 ohms) is preferably present or maintained between the stump and the conductive region thereby achieving one of the needs noted above.

5 In the claims, means- or step-plus-function clauses are intended to cover the structures described or suggested herein as performing the recited function and not only structural equivalents but also equivalent structures. Thus, for example, although a nail, a screw, and a bolt may not be structural equivalents in that a nail relies on friction between a wooden part and a cylindrical surface, a screw's helical surface positively
10 engages the wooden part, and a bolt's head and nut compress opposite sides of a wooden part, in the environment of fastening wooden parts, a nail, a screw, and a bolt may be readily understood by those skilled in the art as equivalent structures.

Having described at least one of the preferred embodiments of the present invention with reference to the accompanying drawings, it is to be understood that the
15 invention is not limited to those precise embodiments, and that various changes, modifications, and adaptations may be effected therein by one skilled in the art without departing from the scope or spirit of the invention as defined in the appended claims.

ABSTRACT OF THE DISCLOSURE

The present invention relates to a supporting sleeve for a leg or arm stumps, namely a liner. The liner includes a sleeve made of an elastomeric and electrically
5 insulating material that surrounds the stump starting from the distal end thereof. The
sleeve has at least in part a surrounding layer made of a suitably conductive material.

IN THE CLAIMS

Kindly amend the claims as follows:

1. -13. (Cancelled)

5

14. (Previously presented) A supporting member for limb stumps, namely a liner, comprising:

a sleeve member further comprising at least an elastomeric material;

said elastomeric material being elastic and electrically insulating;

10

said sleeve member defining a cavity for receiving a distal end of a stump;

portions of said elastomeric material bounding said cavity for receiving said

stump;

said sleeve member further comprising a surrounding layer; and

said surrounding layer composed of a conductive material.

15

15. (New) A supporting sleeve for a stump, namely a liner, comprising:

a sleeve member having a shape to bound at least a distal end of said stump;

said sleeve member being at least partially an elastic and an electrically insulating material; and

20

said sleeve member further comprises an electrically conductive layer bounding at least a portion of said stump.

16. (New) A supporting sleeve for a stump, according to claim 15, wherein:

said electrically conductive layer is positioned externally to said sleeve member.

25

17. (New) A supporting sleeve for a stump, according to claim 16, wherein:

said electrically conductive layer includes at least one of an electrically conductive elastomeric material, an electrically conductive textile material, an electrically conductive ceramic composite, and electrically conductive plastic material.

5 18. (New) A supporting sleeve for a stump, according to claim 15, wherein:

said electrically conductive layer is a matrix of an electrically conductive material enclosed by an elastic material.

19. (New) A supporting sleeve for a stump, according to claim 18, wherein:

10 said matrix is one of an ordered and a disordered assembly of thread members of an electrically conductive material.

20. (New) A supporting sleeve for a stump, according to claim 15, further comprising:

15 means for forming a electrically conductive region between said stump and said electrically conductive layer.

21. (New) A supporting sleeve for a stump, according to claim 20, wherein:

said means for forming a conductive region includes a liner cup member at a distal end of said liner.

20

22. (New) A supporting sleeve for a stump, according to claim 20, wherein:

said conductive region is arranged proximate one of said distal end of said stump and a non-distal-end region of said stump within said liner.

25 23. (New) A supporting sleeve for a stump, according to claim 15, further comprising: a liner cup member at a distal end of said liner.

24. (New) A supporting sleeve for a stump, according to claim 23, wherein:

said liner cup member is one of a cup member formed from an electrically conductive material and a cup member coated with an electrically conductive material, whereby said liner cup member is in an electric communication with said electrically
5 conductive layer.

25. (New) A supporting sleeve for a stump, according to claim 20 wherein:

a measured electrical resistance between a surface of said stump installed in said liner and said conductive region is less than about 10^5 ohms.

10

26. (New) A supporting sleeve for a stump, according to claim 20, further comprising:

means for enabling a secure connection between said supporting sleeve and an external prosthesis shaft member.

15 27. (New) A supporting sleeve for a stump, according to claim 20, further comprising:

said means for enabling a secure connection being one of an electrically conducting means and an electrically insulating means.

28. (New) A supporting sleeve for s stump, according to claim 15, further comprising:

20 means for forming an electrically conductive region between said stump and one of said electrically conductive layer and a liner cup electrically connected to said electrically conductive layer and positioned proximate said distal end of said stump.

29. (New) A supporting sleeve for a stump, namely a liner, comprising:

25 a sleeve member having a shape to bound at least a distal end of said stump;

said sleeve member being at least partially an elastic and an electrically insulating material;

said sleeve member further comprises an electrically conductive layer bounding at least a portion of said stump;

5 said electrically conductive layer is not in direct contact with said distal end of said stump; and

means for forming a electrically conductive region between said stump and said electrically conductive layer.

REMARKS

The enclosed substitute specification, submitted under 37 C.F.R. §§1.121 and
5 1.125, replaces the previous specification with a format confirming to the requirements
of the US Patent Office.

No new matter has been added.

Claims 14-29 are pending in the application. Claims 1-13 are canceled.

It is noted that this submission is being filed concurrently with a second
10 preliminary amendment to the claims under 37 C.F.R. §1.121.

While no fees are believed due with this submission, other than those enclosed
herewith, should additional fees be due or the return of over payments necessary,
authority is provided to access Deposit Account No. 50-2920.

In the spirit of condensed and streamlined practice, if the Examiner believes that
15 a telephone conference would be of value, the Examiner is respectfully requested to call
the undersigned counsel for a prompt response.

Early and favorable action on the merits is respectfully requested in view of the
enclosed amendments.

Respectfully Submitted,



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Date: November 7, 2005

Attached: Clean version (without markings) under 37 C.F.R. §1.125(c).